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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,517	05/01/2002	Dan L. Eaton	P3230R1C001-168	8146

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,517	EATON ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 09/10/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: the Tables (at least Tables 1, 6 and the Table beginning at page 141) presented in the instant specification do not comply with 37 CFR 1.58(c) because the font size does not meet the minimum requirements.

Appropriate correction is required.

Claim Rejections - 35 USC §§ 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to an antibody that binds the polypeptide of SEQ ID NO:12. The specification asserts a number of utilities for the polypeptide, the encoding nucleic acid and antibodies that bind the polypeptide, however, these utilities are not specific and substantial or well established. For example, in Example 11 (page 124), it is asserted that the polypeptide may be used as an

antigen to make antibodies. Because neither the physiological nor the clinical significance of the polypeptide is known, and because the prior art does not support a very close structural relationship to a well described family of known proteins by both structure and function, the polypeptide does not have utility as required by 35 USC 101. If the polypeptide antigen does not have utility, then the antibody which binds it (or method of making the antibody) does not have a specific and substantial utility.

The specification contemplates using the claimed antibodies in diagnostic assays for the protein. However, since the protein has no utility, there is no utility for detecting the protein. Use of the antibodies to purify the protein are contemplated, however, there is no utility found here because, again, the protein lacks utility. The specification further contemplates use of the claimed antibodies for treatment of cancer, however, there is no disclosure of a disease or cancer that is related to the protein to which the claimed antibodies bind (PRO 300), therefore, utility is not found here.

Another assertion of utility is in drug screening and rational drug design (Examples 12 and 13, respectively). The methods involve screening for "agents which can affect a PRO polypeptide-associated disease or disorder" (page 135, paragraph [0507]). No disease or disorder is known to be associated with the claimed polypeptide or encoding polynucleotide. In order to discern a utility for the claimed polypeptide through drug screening in the absence of guidance about which type of disease or disorder the polypeptide causes or how its involvement could lead to treatment, screening for drugs by using the polypeptide

would still require further and undue experimentation to determine the significance of an agent that somehow influenced the polypeptide's function.

Another possible utility comes for the finding that the encoding polynucleotide is "more highly expressed" in normal lung as compared to lung tumor tissue (Example 18 at pages 140-141). There is no guidance on how to use this information. No levels (relative or absolute) are disclosed. This information is too sparse to allow the encoding polynucleotide to be used as a diagnostic marker for lung tumors. Further, even if the polynucleotide had utility as a tumor marker, the encoded polypeptide has no such utility since there is no reason to suspect that there is alteration of polypeptide sequence or amount in lung tumors *versus* normal tissue, and therefore, no use for the antibody that binds it. It is not known what the protein does or if the level of the protein of SEQ ID NO:12 lung tissue corresponds to nucleic acid transcript level, *i.e.*, if decreased gene amplification in tumors corresponds to a decrease in amount of expressed protein.

For these reasons, there is no substantial and specific utility for the claimed antibody.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth

above, one skilled in the art clearly would not know how to use the claimed invention.

It would require significant further experimentation to be able to use the claimed antibody because no definite function or directly associated disease has been determined for the protein of SEQ ID NO:12 to which the claimed antibody binds, and there is no definite function supported by the prior art. No function can be reasonably assigned based on its homology to another protein(s). Using the claimed antibody would require undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "[t]he antibody of Claim 1 which specifically binds". However, the term "specifically" is one of degree for which no guidance is present in the specification for determining the metes and bounds of what is to be encompassed by "specifically" as opposed to the previously recited "binds". Therefore, the claim is indefinite.

35 U.S.C. § 102

The following rejections under 35 U.S.C. § 102 is made under the assumption that the effective filing date for the instantly claimed invention is 05/01/2002, which is the actual filing date of the instant application. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. §120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the new claimed invention. Because the instant application does *not* meet the requirements of 35 U.S.C. § 112, first paragraph, for the reasons given above and it is a continuing application of Serial Number 10/006,867, the prior application also does not meet those requirements for the claimed invention and, therefore, is unavailable under 35 U.S.C. § 120.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/16318.

WO 01/16318 teaches the polypeptide of SEQ ID NO:12, which is 100% identical to SEQ ID NO:12 of the instant application as well as antibodies that bind to the polypeptide of SEQ ID NO:12 (see Figure 12). Antibodies are

disclosed which are monoclonal, humanized, fragments and labeled (see pages 67-73) Therefore, the claims are anticipated by the prior art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud